Project to Develop the
International Classification for Patient Safety

Report on the Results of the Web-Based
Modified Delphi Survey of the
International Classification for Patient Safety
Overview

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Foreword

Between August and November 2006, the Drafting Group set up by the World Health Organization’s World Alliance for Patient Safety to develop an International Classification for Patient Safety (ICPS) carried out a two-stage, web-based modified Delphi Survey (Delphi Survey) to test the relevance and acceptability of the ICPS. This report provides some background information, definitions of key concepts, a description of the iterative process of the Delphi Survey, and the results of the analysis. It is divided into three sections:

- **Introduction**: An overview of the background and rationale for the ICPS
- **Key concepts, Definitions and Preferred Terms**: A narrative describing the relationships between key concepts linking preferred terms and definitions, with diagrams showing these links and the conceptual framework underpinning the ICPS
- **The Delphi Process**: A description of how respondents were recruited, how their responses were collated with results of the two surveys and a description of the major revisions made to the ICPS conceptual framework and classes, with the rationale for these revisions

The Drafting Group sincerely thanks those who dedicated their valuable time to respond to the Delphi Survey. As shown in this report, the input had a significant impact on the development of the ICPS.
Introduction

Although the results of the first large-scale study of adverse events were published over thirty years ago, the field of patient safety has only gained widespread attention in the last decade. In this time, there has been a rapid increase in the number of publications and reports in this area, but interpretation and comparison have been compromised by a lack of common understanding and language. A need was thus identified for a comprehensive classification, populated by concepts with agreed definitions, which should be described by “preferred terms” from the major languages of the world. The consistent use of such terms and concepts in conjunction with a comprehensive but adaptable classification will pave the way for researchers to understand each others’ work, and will facilitate the systematic collection, aggregation and analysis of relevant information from all available sources, allowing comparisons between facilities and jurisdictions, and over time. The classification should be applicable across the full spectrum of healthcare from primary care to highly specialized areas and should be able to be used in conjunction with existing processes and systems.

An opportunity to address this need was presented by the launch of the World Alliance for Patient Safety of the World Health Organization (WHO). A group was formed under the auspices of the World Alliance and some general principles agreed. It was decided that a classification (an arrangement of concepts based on similarities) instead of a taxonomy (a set of rules to name entities based upon their location within a particular structure) was needed. It was decided to use concepts and terms with meanings as close as possible to those in colloquial use and to avoid long definitions with several “qualifiers”, but instead to start with simple, basic definitions, and then “build” by defining the key terms used in these definitions. This makes it necessary to read the terms and their definitions in the sequence provided in the next section.

The first requirement was to develop and agree on an underlying conceptual framework. After reviewing the relevant literature and examining some existing classifications, an initial version of a framework was developed, with definitions of a few basic concepts. This framework and its accompanying concepts were subjected to a two-stage web-based Delphi review which yielded some 700 responses. These responses led to further discussion amongst the drafting group, and an iterative process was undertaken by which the framework, concepts and definitions were progressively refined and improved. This process and how it influenced and led to revisions of the initial framework, classes, concepts and definitions, together with the responses to the Delphi respondents, form the last two sections of this document.

The iterative process was rendered difficult because, at the start, there was no agreement on many commonly used concepts, terms and definitions. Therefore, initial definitions of key terms were used from a previous iterative process, which had taken into consideration many definitions from over 60 sources of information. For example, 16 definitions for “error” and 14 for “adverse event” had been identified and considered before arriving at agreed definitions for these concepts. It was decided to recommend that certain terms not be used in the context of the ICPS, because they have different meanings in different jurisdictions (for example, negligence and liability), because they have discipline-specific meanings (such as accident (aircraft hull loss) in aviation), because they have a range of meanings (complication, misadventure, sequela) or because they overlap with other terms we have decided to use (such as nosocomial and iatrogenic which have been replaced by “healthcare-associated”).

The trail of development of the definitions has therefore been complex, as they are adaptations from several sources and from previous Delphi and other consultative processes. The main consideration in coming up with the definitions was that they should convey the appropriate meaning and be brief and clear, without unnecessary or redundant qualifiers. They should also, whenever reasonable, be consistent with concepts from other terminologies and classifications in the Family of International Classifications of the WHO.

The resulting conceptual framework for the ICPS is shown in Figure 1. How some key terms and concepts relate to the ICPS is shown in Figure 2. In the next section a narrative, in a logical sequence, incorporates the definitions of the key concepts with the preferred terms and some descriptions and comments. The definitions are listed in Table I in the sequence in which they are discussed in the narrative, and the terms defined are listed in alphabetical order in Table 2.

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Figure 1. Conceptual Framework for the International Classification for Patient Safety

Conceptual Framework for the International Classification for Patient Safety

Legend: The solid lines enclose the 10 major classes of the ICPS and represent the semantic relationships between them. The dotted lines represent the flow of information.
Key Concepts, Definitions and Preferred Terms

As foreshadowed in the Introduction, in order to keep the definitions as succinct as possible, concepts are progressively introduced so as to allow understanding to be “built”, starting with the terms in the title of the ICPS (classification, patient, safety). The terms in **bold** have been deemed ICPS preferred terms; where terms have been highlighted in this way, the agreed definitions follow.

A **classification** is an arrangement of **concepts** (bearers or embodiments of meaning) into **classes** (groups or sets of like things, such as “Contributing Factors”, “Incident Types” and “Patient Outcomes”) and their subdivisions to express the **semantic relationships** between them (the way in which they are associated with each other on the basis of their meanings). For example, Contributing Factors precede and play a role in the generation of any particular Incident Type. Similarly, Mitigating Factors are associated with Incident Type and Outcomes, as steps cannot be taken to interfere with the progression of an incident until its nature has been determined, and the outcomes will not occur until these attempts have reached their conclusion.

The ICPS allows assignment of features of incidents on the basis of common characteristics; this facilitates their later extraction for analysis. Each class has hierarchically arranged subdivisions populated by concepts (for example, “fatigue/exhaustion” under the class “Contributing Factors”). Concepts impart the essence of a notion using a term. Concepts may be represented by a number of terms that allow for regional dialects, different languages, clinicians, disciplines and hospital preferences. Preferred terms to describe the concepts have been chosen as “natural categories” (see below), or terms with meanings as close as possible to those in colloquial use.9

Concepts may inherit characteristics from their “parents” (a parent-child or subsumption relationship), or represent selected agreed qualities, properties or features of the concept in question which are not inherited (an “attribute” relationship). For example, “endotracheal tube” and “tracheotomy tube” are children of “artificial airway”, whereas the list of medical devices has an attribute-type relationship to the incident type “medical devices/equipment/property”, and is not one of its children. Concepts have been organized hierarchically in the classification according to natural mapping. Natural mapping is the grouping of the subsets or attributes of a class or concept in a representation reflecting the real world.16

A **patient** has been defined as a person who is a recipient of healthcare and **healthcare** has been defined as services received by individuals or communities to promote, maintain, monitor or restore health. For the purposes of the ICPS, patients are referred to rather than clients, tenants or consumers, although it is recognized that a healthy pregnant woman, a child undergoing immunization, the occupant of a halfway house or an adolescent seeking counseling may not be regarded, and may not regard themselves, as patients. Healthcare is not limited to medical care provided by others, and includes self-care. **Health** has been defined “as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”, consistent with the World Health Organization definition.

**Safety** has been defined as freedom from hazard, and **hazard** as a circumstance, agent or action which can lead to or increase risk. A **circumstance** has been defined as any factor connected with or influencing an event, agent or person(s); an **event** as something that happens to or involves a patient; and an **agent** as a substance, object or system which acts to produce change. For the purposes of the ICPS it is implicit that all these terms (and others, such as quality and outcome) are meant to be interpreted in the context of patient safety.

**Patient safety** is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare. **Healthcare-associated harm** is harm arising from or associated with plans or actions taken during the provision of health care rather than an underlying disease or injury.

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A patient safety incident is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient, and has a more constrained meaning than the term incident which, when used in a general context, has a wider meaning as an event or circumstance which could have resulted, or did result, in harm to any person and/or a complaint, loss or damage. Please note for purposes of the ICPS, a patient safety incident will be hereafter referred to as an incident.

The use of the term “unnecessary” in the definition of patient safety incident is in recognition that errors, violations, patient abuse and deliberately unsafe acts occur in healthcare and are unnecessary incidents, whereas certain forms of harm, such as an incision for a laparotomy, are necessary. The former are incidents, whereas the latter would not be regarded as one.

Incidents may arise from both unintended and intended acts. Errors are, by definition, unintentional, whereas violations are intentional, even though they may become routine in certain contexts. An error may be defined as a failure to carry out a planned action as intended or application of an incorrect plan, and may manifest by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission), at either the planning or execution phase. Thus, if it is agreed that screening for bowel cancer should be by regular testing for occult blood, then a screening colonoscopy in the absence of prior occult blood testing comprises an error of commission (over servicing), and a failure to arrange testing for occult blood an error of omission (under servicing). A violation implies deliberate deviation from an operating procedure, standard or rule. Both errors and violations increase risk, even if an incident does not actually occur. Risk is the probability that an incident will occur.

An adverse event is an incident which results in harm to a patient. Harm implies impairment of structure or function of the body and/or any deleterious effect arising therefrom. Harm includes disease, injury, suffering, disability and death and may thus be physical, social or psychological. Disease is defined as a physiological or psychological dysfunction, injury as damage to tissues caused by an agent or circumstance and suffering as the experience of anything subjectively unpleasant. Suffering includes pain, malaise, nausea, vomiting, depression, agitation, alarm, fear and grief. Disability implies any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm. A near miss is an incident that did not cause harm (also known as a close call).

A contributing factor is defined as a circumstance, action or influence (such as poor rostering or task allocation) which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident. Contributing factors may be external (ie not under the control of a facility or organization), organizational (such as unavailability of accepted protocols), be related to a staff factor (a cognitive or behavioral defect in an individual, a lack of supervision, poor team work or inadequate communication) or be related to a patient factor (such as behavior).

Incidents are classified into a number of different incident types. An incident type is a descriptive term for a category made up of incidents of a common nature, grouped because of shared agreed features. An incident type is a “parent” natural category under which many concepts (also comprising natural categories) may be grouped; they may be “children” of the parent incident type or attributes (see above under the description of classes, concepts and natural mapping).

A natural category is a descriptor (usually a short phrase) which is brief, easily and commonly understood. It captures the essence of an event or circumstance or of associated characteristics or attributes and is not constrained by being restricted to any class or property. To take an example from the workplace – 40 of 100 incident reports describing why staff are late for work might be assigned to the following natural categories: could not find car key; child sick – no other carer; had a puncture or flat tyre; alarm clock did not go off; or usual car park full. These phrases capture the essence of each incident and most observers would categorize them in the same way (e.g., a higher rate of inter-rater reliability). Natural categories constitute an informal classification system, used by a specific professional or cultural group. They reflect a social consensus about what matters, or what is worthy of notice, in a given context. In this case, the context is patient safety.
Incident types are not exclusive categories. An incident may need to be assigned to several incident types, although a “business rule” may be developed to allow a “principal” incident type to be nominated so that all incidents may be counted. One rule is to nominate the incident which led most directly to any harm or potential harm as the principal incident type. Thus, for example, for an incident in which an infusion pump was set up wrongly and delivered an overdose of a sedative, causing respiratory arrest, the drug overdose (the medication incident type) would be selected as the principal incident type rather than the equipment problem. Other examples of incident types are healthcare associated infection, documentation problems and problems with a clinical administration process.

**Patient characteristics** are selected attributes of a patient, such as patient demographics or the reason for presentation to a healthcare service. **Attributes** are qualities, properties or features of someone or something. **Incident characteristics** are defined as selected attributes of an incident, such as care setting, hospital treatment status, specialties involved and timing or date of the incident.

Terms commonly used in relation to medication incidents include adverse reactions and side effects. An **adverse reaction** is defined as unexpected harm arising from a justified action where the correct process was followed for the context in which the event occurred. Recurrence of a known adverse reaction may be preventable (such as an allergic reaction to a drug, by avoiding re-exposure). A **side effect** is a known effect, other than that primarily intended, relating to the pharmacological properties of a medication. An example of an adverse reaction would be unexpectedly getting neutropenia when that particular drug is not known to have this effect. An example of a side effect would be when nausea, pruritis or urinary retention are encountered when morphine has been given to alleviate pain.

It is useful to try to identify when an incident is preventable. **Preventable** has been defined as being accepted by the community as avoidable in the particular set of circumstances.

**Detection** is defined as an action or circumstance that results in the discovery of an incident. This may be by noticing an error via a monitor or alarm, by a change in patient condition or by an audit, review or risk assessment. Detection mechanisms may be part of the system (such as low pressure disconnect alarms in breathing circuits) or may result from a checking process or from vigilance and “situation awareness”.

A **mitigating factor** is defined as an action or circumstance which prevents or moderates the progression of an incident towards harming a patient. The damage mechanism has already started, but has not yet led to the maximum possible harm.

The term “error recovery” has been used to describe the combined detection and mitigation sequence. In this context recovery does not refer to clinical recovery (recuperation) but to the process of recovering from an incident that has started. An example of error recovery would be reconnecting a breathing circuit after a disconnect alarm had given warning that there was a disconnection. By collecting information about how and why “saves” are made, system design, training and education can be informed.

**Patient outcome** is defined as the impact upon a patient which is wholly or partially attributable to an incident. Where harm has occurred, the **degree of harm** is defined as the severity and duration of any harm, and the treatment implications, that result from the incident. It would seem, from first principles, desirable to record the nature, severity and duration of harm separately. However, in practice, there are substantial problems in doing this and nearly all attempts to link degree of harm conflate these parameters. **Organizational outcome** is defined as the impact upon an organization which is wholly or partially attributable to an incident. Examples would be adverse publicity and additional use of resources.

**An ameliorating action** is an action taken or circumstance altered to make better or compensate any harm after an incident. Patient ameliorating factors are actions taken or circumstances altered to make good any harm to a patient, such as fixing a fracture after a fall, whereas healthcare system ameliorating factors reduce any loss or damage to an organization arising from an incident. For example, good public relations management after a well publicized disaster will ameliorate any long-term effects on the reputation of a facility.
**Actions taken to reduce risk** are defined as actions taken to reduce, manage or control the harm, or probability of harm, associated with an incident. An action can relate directly to incidents and contributing factors, detection, mitigating factors or ameliorating actions and can be pro-active or reactive. Pro-active actions may be identified by techniques such as failure mode and effects analysis and probabilistic risk analysis, whereas reactive actions are those taken in response to insights gained after an incident (see root cause analysis, below, for an example).

**Resilience** refers to the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents. Resilience allows an organization to “bounce back” to its original ability to provide core functions as soon as possible after incurring damage.

A number of terms are commonly used with respect to organizational management. **Accountable** is defined as being held responsible. The terms negligence and liability are listed below, but are not considered core definitions as these may vary depending on the jurisdiction. **Quality** is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. **System failure** refers to a fault, breakdown or dysfunction within an organization’s operational methods, processes or infrastructure. Factors contributing to system failure can be latent (hidden or apt to elude notice) or apparent, and can be related to the system, the organization or a patient. An example of a latent factor would be a breathing circuit disconnect alarm with no power failure warning or battery backup. **System improvement** is defined as the result or outcome of the culture, processes and structures that are directed towards the prevention of system failure and the improvement of safety and quality. A process to counter the latent failure just described would be to modify the equipment to alarm when the power supply is compromised, or to always use an additional device such as expired air capnography set up so as to alarm if carbon dioxide is not detected. Finally, **root cause analysis** is defined as a systematic iterative process whereby the factors which contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking “why?” until the underlying root causes (contributing factors/hazards) have been elucidated. “Why” should be iteratively asked until the investigating team runs out of facts – they should not guess or speculate. The team should also stop the process when the identified contributing factors or hazards require counter measures which are beyond the influence of the organization. These are known as “stopping rules”, and help to determine when a root cause analysis team should stop the investigative process and move on to defining the problems and recommending corrective strategies.

Concepts defined and terms chosen so far simply represent a collection of basic building blocks to enhance the study of patient safety. Changes will be necessary as our understanding widens and needs are identified. Translation into other major languages will be necessary and has been started. There are more concepts which will need to be defined, and decisions made with respect to which terms should be preferred and which terms avoided. Certain qualifiers should be regarded as implicit when these terms are used in the context of the ICPS. For example, it should be assumed that the term “incident” refers to a patient safety incident, implying harm or potential harm associated with harm. The same applies to terms such as quality and system failure. Used in this way the concepts defined and terms chosen so far will facilitate understanding and transfer of information relevant to patient safety amongst the increasing number of people with an interest in this area.
Figure 2. The Conceptual Framework of the ICPS Showing Links to Preferred Terms

Legend: The solid lines enclose the 10 major classes of the ICPS and represent the semantic relationships between them. The dotted lines link relevant preferred terms which have been defined in the text. The numbers represent the sequence in which they appear in the text and in Tables 1 and 2.
Table 1. List of Preferred Terms and Definitions for Key Concepts

1. **Classification**: an arrangement of **concepts** into **classes** and their subdivisions to express the **semantic relationships** between them.
2. **Concept**: a bearer or embodiment of meaning.
3. **Class**: a group or set of like things.
4. **Semantic relationship**: the way in which things (such as **classes** or **concepts**) are associated with each other on the basis of their meaning.
5. **Patient**: a person who is a recipient of **healthcare**.
6. **Healthcare**: services received by individuals or communities to promote, maintain, monitor or restore **health**.
7. **Health**: a state of complete physical, mental and social wellbeing and not merely the absence of **disease** or infirmity.
8. **Safety**: freedom from **hazard**.
9. **Hazard**: a **circumstance**, **agent** or action that can lead to or increase risk.
10. **Circumstance**: any factor connected with or influencing an **event**, **agent** or person(s).
11. **Event**: something that happens to or involves a **patient**.
12. **Agent**: a substance, object or system which acts to produce change.
13. **Patient Safety**: freedom, for a patient, from unnecessary harm or potential harm associated with **healthcare**.
14. **Healthcare-associated harm**: harm arising from or associated with plans or actions taken during the provision of healthcare rather than an underlying **disease** or **injury**.
15. **Patient safety incident**: an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**.
16. **Error**: failure to carry out a planned action as intended or application of an incorrect plan.
17. **Violation**: deliberate deviation from an operating procedure, standard or rules.
18. **Risk**: the probability that an **incident** will occur.
19. **Adverse event**: an **incident** which results in **harm** to a **patient**.
20. **Harm**: impairment of structure or function of the body and/or any deleterious effect arising there from.
21. **Disease**: a physiological or psychological dysfunction.
22. **Injury**: damage to tissues caused by an **agent** or **circumstance**.
23. **Suffering**: the experience of anything subjectively unpleasant.
24. **Disability**: any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present **harm**.
25. **Near Miss**: an **incident** that did not cause **harm**.
26. **Contributing Factor**: a **circumstance**, action or influence which is thought to have played a part in the origin or development of an **incident** or to increase the **risk** of an **incident**.
27. **Incident type**: a descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features.
28. **Patient characteristics**: selected **attributes** of a **patient**.
29. **Attributes**: qualities, properties or features of someone or something.
30. **Incident characteristics**: selected **attributes** of an **incident**.
31. **Adverse reaction**: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
32. **Side effect**: a known effect, other than that primarily intended, related to the pharmacological properties of a medication.
33. **Preventable**: accepted by the community as avoidable in the particular set of circumstances.
34. **Detection**: an action or **circumstance** that results in the discovery of an **incident**.
35. **Mitigating factor**: an action or **circumstance** which prevents or moderates the progression of an **incident** towards harming a **patient**.
36. **Patient outcome**: the impact upon a patient which is wholly or partially attributable to an **incident**.
37. **Degree of harm**: the severity and duration of harm, and the treatment implications, that result from an **incident**.
38. **Organizational Outcome**: the impact upon an organization which is wholly or partially attributable to an incident.
39. **Ameliorating action**: an action taken or circumstances altered to make better or compensate any harm after an incident.
40. **Actions taken to reduce risk**: actions taken to reduce, manage or control the harm, or probability of harm associated with an incident.
41. **Resilience**: The degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents.
42. **Accountable**: being held responsible
43. **Quality**: the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
44. **System failure**: a fault, breakdown or dysfunction within an organization’s operational methods, processes or infrastructure.
45. **System improvement**: the result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and the improvement of safety and quality.
46. **Root cause analysis**: a systematic iterative process whereby the factors which contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why? until the underlying root causes have been elucidated.

**Table 2. List of Preferred Terms for Key Concepts in Alphabetical Order**

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<td>System improvement (45)</td>
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The Delphi Process and the Resulting Revisions

The initial conceptual framework, developed to represent an underlying information model using classes and concepts, was designed to accommodate patient safety data and information obtained from a variety of sources (e.g. reporting systems, incident reports, root cause analyses, medical record reviews, complaints, consumer reporting, sentinel events, coroner’s reports, medico-legal cases). It consisted of the following ten high level classes (shown in the boxes in Figure 3).

Figure 3.

The original conceptual framework and its accompanying concepts were subjected to a two-stage, web-based modified Delphi survey. Experts in the fields of patient safety, health policy legislation, reporting systems, safety and quality control, classification theory and development, health informatics, consumer advocacy, law and medicine were invited to participate in the Delphi Survey. Each received a personalized invitation to participate in the Delphi process which contained a unique link to the electronic surveys. Input was also sought from a wider stakeholder constituency. Open invitations to take part in the Delphi process were placed in an article published in the International Journal for Quality in Health Care and on the websites of the World Health Organization’s World Alliance for Patient Safety, the Australian Patient Safety Foundation, The Joint Commission and the National Patient Safety Agency. Delphi participants were asked to complete two rounds of surveys. Only those who provided input during the first round were asked to participate in the second round. Respondents were assured confidentiality but not anonymity.

Round One Survey (see Appendix A)

The first round of the web-based Delphi survey was from 18 August to 22 September 2006. The Round One survey was comprised of the following sections:

1. Participant demographics – In addition to age, gender, country and native language, questions include whether the respondent was a health care professional, what expertise he/she had based on the criteria listed above, and whether he/she had practical experience in collecting, classifying and/or analysing patient safety data.

2. The conceptual framework – Questions included:
   a. Is the conceptual framework an adequate model for use in describing a patient safety event? Possible responses were “yes”, “yes with modification”, “no” or “unsure”. Respondents who answered “yes with modification” or “no”, were asked to suggest improvements and provide a rationale for the suggested changes.
   b. Do you believe any classes are missing from the conceptual framework? Respondents who answered “yes” were asked to indicate which class(es) were missing, where the class(es) should be incorporated and to provide a rationale for adding the suggested class(es).
   c. Do you believe the conceptual framework is a meaningful and useful tool for translating disparate information into a format conducive to learning and improving patient safety? Possible responses were “strongly agree”, “agree”, “neither agree nor disagree”, “disagree” or “strongly disagree”. Respondents who answered “neither agree nor disagree”, “disagree” or “strongly disagree” were asked to explain why he/she chose the particular answer.

3. Definitions – Respondents were asked to review the terms and definitions for each of the ten classes contained within the conceptual framework for clarity, precision and accuracy. Respondents who believed a term or definition was unclear, were asked to provide an explanation as to why the term or definition was unclear and to provide an alternative term or definition, the relevant reference(s) to the source(s) and a rationale for replacing the existing term or definition with the one provided.

4. Meaningfulness and usefulness of each of the ten classes within the conceptual framework – Respondents were asked to react to the following statement for each of the ten classes: The class, [class term (ie Event Types)], is a meaningful and useful class within the International Patient Safety Event Classification. Possible responses were “strongly agree”, “agree”, “neither agree nor disagree”, “disagree” or “strongly disagree”. Respondents who answered “neither agree nor disagree”, “disagree” or “strongly disagree” were asked to explain why he/she chose the particular answer.

5. Overall comments were sought.

Round One Survey Results

A total of 253 individuals speaking 29 different languages from 43 countries responded to the first round of the Delphi survey. One hundred sixty one (161) responded to the personalized invitation letter sent by the Drafting Group; the remaining 92 were responses to the open invitation.

The respondents included health care professionals, health policy experts, developers/manager of patient reporting systems, patient/public representatives, academicians, representatives from professional associations for a variety of health care specialties, representatives from litigation, classification/taxonomy experts, risk managers and representatives from organizations responsible for assessing and monitoring patient safety performance. Eighty one percent (81%) had practical experience in collecting, classifying and/or analysing patient safety data.
Of those who responded:

- 86% believed the conceptual framework was an adequate model for use in describing a patient safety event;
- 81% believed the conceptual framework was a meaningful and useful tool for translating disparate information into a format conducive to learning and improving patient safety;
- 50% responded that the conceptual framework was missing at least one class. However, upon reading their comments, it became apparent that most of the respondents were referring to concepts they felt should be included within the classes instead of classes that should be included within the conceptual framework.
- 82% felt that the terms and definitions for each of the 10 classes contained within the conceptual framework were clear, precise and provided an accurate representation of the nature, properties, scope and essential qualities of the concept; and
- 89% felt that all 10 classes within the conceptual framework were meaningful and useful.

All comments were reviewed. The main idea elicited from the comments was the need for clarification, particularly surrounding the:

- Purpose of the classification;
- Structure and depth of the conceptual framework;
- Intention of the classification to include both adverse events and near misses;
- Ability of the conceptual framework to serve as a model to classify a patient safety event; and
- Concepts contained within each of the classes.

**Modifications made to the Classification as a result of Round One Feedback**

The members of the classification task forces (Delphi Process, Conceptual Framework and Conceptual Identification) considered the results from Round One and made the following modifications to the Classification.

1. An overview of the classification was developed. The overview
   a. Provides background on the development of the classification;
   b. Differentiates and discusses the relationship between a classification and a reporting system;
   c. Describes the classification, including a detailed explanation of its structure and composition;
   d. Explicitly illustrates how the concept of a patient safety event (both adverse and near miss events) were captured by the classification.
   e. Delineates each classification tree and the concepts contained therein; and
   f. Demonstrates how to classify an event using the classification’s conceptual framework as a model, including two examples.
2. The definitions of the terms for the following classes were clarified:
   a. Event Type (adverse events and near misses)
   b. Patient impact/Outcomes
   c. Contributing Factors
   d. Actions Taken
   e. Recovery Factors

3. The relationship between and among Contributing Factors, Preventive Factors, Recovery Factors and Mitigating Factors was explained.

**Round Two Survey (see Appendix B)**

The second round of the Delphi survey took place from 1\(^{st}\) November – 27\(^{th}\) November, 2006.

The Round Two survey consisted of the same sections and questions as the Round One survey, with the one exception and two additions:

1. Exception – Because the Round Two survey was sent only to those who responded in Round One, the participant demographics section was not included. The information had already been captured.

2. Additions –
   a. The overview of the Classification at the beginning of the survey
   b. Quantitative and qualitative feedback from Round One for each question, as well as the responses to the comments and the modifications to the Classification based upon the results of the first survey.

**Round Two Survey Results**

75 out of 253 invited participants responded to the Round Two survey (response rate = 29.6%). Although 75 individuals responded, only 68 completed the entire survey.

Again, the respondents included health care professionals, health policy experts, developers/managers of patient reporting systems, patient/public representatives, academicians, representatives from professional associations for a variety of health care specialties, representatives from litigation, classification/taxonomy experts, risk managers and representatives from organizations responsible for assessing and monitoring patient safety performance.

Of those who responded:

- 93.3% (69/75 responses) believed the conceptual framework was an adequate model for use in describing a patient safety event;

- 83.1% (59/71 responses) believed the conceptual framework was a meaningful and useful tool for translating disparate information into a format conducive to learning and improving patient safety;

- 13.2% (9/68 responses) thought that the conceptual framework was missing at least one class. Again, upon reading their comments, it became apparent that most of the respondents were referring to concepts they felt should be included within the classes instead of classes that should be included within the conceptual framework.
- 89% (61/68 respondents) felt that the terms and definitions for each of the 10 classes contained within the conceptual framework were clear, precise and provided an accurate representation of the nature, properties, scope and essential qualities of the concept; and

- 82% (61/68 respondents) felt that all 10 classes within the conceptual framework were meaningful and useful.

All comments were reviewed. The number of comments ranged from five (5) to 14 per question. There were 27 general comments made.

The main themes to emerge were:

- The need for field testing and an instruction manual
- The conceptual framework is too complex for the average, every day user
- Confusion regarding the relationship between Recovery Factors, Mitigating Factors and Actions Taken
- Confusion regarding the role of the Preventive Factors class
- Structurally, “Patient Procedures” belongs under the Event Characteristics class instead of Patient Characteristics class
- Concern over the term for and purpose of Recovery Factors
- Concern over the “Behaviour” concept

**Modifications made to the Classifications as a Result of Round Two Feedback**

The Drafting Group considered the results from Round Two during the 13-14 December 2006 meeting and made the following modifications;

1. The conceptual framework was revised to clarify the purpose of each class and to explicitly show the relationships among and between them. Specifically;

   a. The actions taken as a direct result of the patient safety event were separated out from the Actions Taken class. The Actions Taken class was then renamed “Actions Taken to Reduce Future Risk”. The concepts in this class were narrowed to focus on organizational actions taken as a result of the patient safety event to inform the development of strategies to reduce the risk of the patient safety event reoccurring (eg. learning cycles);

   b. The Preventive Factors class was renamed to “Before Event (Preventive) Factors”;

   c. The Recovery Factors class was renamed to “During Event (Recovery) Factors”. The “Clinical Actions Taken” concepts were moved from the Actions Taken class to this class to indicate the actions taken as a direct result of the patient safety event;

   d. The Mitigating Factors class was renamed to “After Event (Mitigating) Factors”. The “Clinical Actions Taken” concepts were also included in this class to indicate the actions taken as a direct result of the patient safety event; and

   e. “Patient Procedures” was moved from the Patient Characteristics class to the Event Characteristics class.
2. The concepts contained within the third level concept “Behaviour” (Contributing Factors, Human and Performance Factors, Behaviour) were modified:

a. “Mistakes (includes accidents, slips and lapses)” was moved from “Behaviour” to the third level concept “Cognitive Related Factors” under Contributing Factors, Human and Performance Factors;
b. “Perception” was moved from Behaviour to the third level concept “Cognitive Related Factors” under Contributing Factors, Human and Performance Factors;
c. “At Risk Behaviour” was retained as a fourth level concept; and
d. The concepts of “Negligence” and “Recklessness” were made fifth level concepts under “At Risk Behaviour”

3. The definitions of the following classes were refined:

a. Contributing Factors
b. Actions Taken – now known as Actions Taken to Reduce Future Risk
c. Preventive Factors – now known as Before Event (Preventive) Factors
d. Recovery Factors – now known as During Event (Recovery) Factors
e. Mitigating Factors – now known as After Event (Mitigating) Factors

Following analysis of the Delphi responses, the conceptual framework was revised as responses revealed an unacceptable level of confusion regarding the relationships between and among the classes; specifically between Contributing Factors, Preventive Factors, Recovery Factors and Mitigating Factors. Many respondents felt the conceptual framework was too complex. The Drafting Group attempted to address these concerns at the December 2006 Drafting Group meeting (see figure 4).

**Figure 4.**
Further Modifications Made Following December 2006 Drafting Group Meeting

After the December 2006 meeting, it was decided to undertake the further review of the Delphi comments. After developing responses to each Delphi comment, and following the development of definitions for the key patient safety concepts outlined in the Key Concepts, Definitions and Preferred Terms section, the conceptual framework was again revised.

The Classes

The Delphi analysis revealed the classes were incomplete and, in some instances, inappropriately organized. The classes were refined to ensure that the concepts are organized hierarchically according to natural mapping (the grouping of subsets or attributes of a class or concept in a representation reflecting the real world as it is perceived) and fall into natural categories (descriptors which are brief, easily and commonly understood).

To summarize:

- Event Types was relabeled Incident Type.
- Patient Impact/Outcomes was relabeled Patient Outcomes.
- Patient Characteristics remained Patient Characteristics.
- Event Characteristics was relabeled Incident Characteristics.
- Contributing Factors was relabeled Contributing Factors/Hazards.
- Actions Taken was deleted.
- Detection was added. To recover, one needs to detect and then mitigate: “to prevent or moderate the progression of an incident”. Recovery is comprised of detection plus mitigation. The revised conceptual framework is an endeavor to reduce the substantial confusion surrounding the intent and meaning of the classes.
- Before Event (Preventive) Factors was revised and relabeled Actions Taken to Reduce Risk as a result of the Delphi analysis. This class encompasses concepts previously contained in the deleted Action Taken class.
- During Event (Recovery) Factors was deleted.
- Mitigating Factors was added in light of the Delphi analysis for the same reason Detection was added. To recover, one needs to detect and then mitigate. Recovery equals detection plus mitigation.
- After Event (Mitigating) Factors was deleted.
- Ameliorating Actions was added. The concepts under this class indicate the actions taken or circumstances altered to make better any harm after an incident
- Organizational Outcomes remained Organizational Outcomes.

The final conceptual framework (shown in Figure 1) continued to organize high level classes into a transparent, theoretical and logical architecture. The labels changed, but the underlying concepts did not.
The classes Incident Type and Patient Outcomes were designed to group events into recognizable categories in clinically meaningful ways so that new events could be promptly characterized and information of past events easily retrieved. This information is fundamental to the description of a patient safety incident. The classes Contributing Factors/Hazards, Patient Characteristics, Incident Characteristics and Organizational Outcomes provide descriptive information. Finally, the classes Detection, Mitigating Factors, Ameliorating Actions and Actions to Reduce Risk or Harm are concepts associated with system resilience and inform learning and analytical processes.

A description of the major revisions to the classes follows:

**Detection and Mitigating Factors**

As noted by the subgroup, there was significant confusion regarding the meanings and purposes of the Recovery Factors, Mitigating Factors, and Preventive Factors classes. The concept of error recovery, derived from industrial science and error theory, is particularly important if learning from patient safety incidents is to occur. Recovery factors are “actions or circumstances that follow detection of an incident and prevent or moderate its progression so as not to result in harm;” thus as Tjerk van der Schaaf’s work suggests, error recovery has a detection phase and an action phase. The subgroup decided to create Detection and Mitigating Factors as classes to signify the detection and action phases and to delete Recovery Factors.

Detection is defined as “an action or circumstance that results in the discovery of an incident” (i.e., the detection phase). For example, an incident could be detected by noticing an error, via a monitor or alarm, by a change in the patient’s status, or via an audit, review or risk assessment. Detection mechanisms may be built into the system as official barriers or informally developed. Mitigating Factors are defined as “actions or circumstances which prevent or moderate the progression of an incident toward harming the patient” (i.e., the action phase). With mitigating factors, a distinction is made between preventing an initial error and minimizing the harm to the patient after the error has already occurred and the start of the damage mechanism triggered. Recovery factors are consequently detected and then mitigated.

**Organizational Outcomes**

The original concepts for this class were adapted from the International Classification of Functioning, Disability, and Health (ICF). These concepts, even as modified, were not fit for purpose for this class. This became clear from the Delphi responses. The revised concepts populating this class have been derived from real world incident reports and are commonly used in the health care field.

**Ameliorating Actions**

Ameliorating Actions is a new class. It was borne from the ambiguity created by mitigation/recovery, action taken and preventive factors. To develop this class the subgroup revisited the literature, reviewed the temporal flow of patient safety incidents, and reviewed real world incident reports. The concepts contained in this class are not circumstances but are actions undertaken by the healthcare professional or organization to “right a wrong.” The concepts signify “doing something”, so the word action has been substituted for factor.

**Actions Taken to Reduce Risk**

A significant outcome of the Delphi analysis was the need to clarify the meaning of, purpose for, and temporal aspect of, the Preventive Factors class. To redefine the concept of this class the subgroup posed the following questions: (1) could the incident have been prevented, or potentially prevented?; (2) what policies, procedures, etc. were in place to prevent or potentially prevent the incident?; and (3) what was done after the incident to prevent future occurrences?
After much discussion, the subgroup concluded that preventive factors were essentially the inverse of contributing factors. The concepts under Actions Taken to Reduce Risk concentrate on steps taken to reduce the risk of reoccurrence of similar incidents. The concepts are not circumstances but circumstances altered; they focus on learning and system resilience efforts. The concept of resilience in the context of the ICPS is somewhat different than in resilience engineering (Hollnagel, Woods, et al.). In the International Classification for Patient Safety, resilience is defined as the degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents. Ameliorating hazards includes “bouncing back” to the original ability to provide core functions as soon as possible after incurring damage.